

MAY - 4 2004

K040376

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

Date Prepared:

February 13, 2004

Submitter's Information:

Sectra Imtec AB
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Trade Name, Common Name, Classification:

Trade Name: Sectra IDS5 Radiology Workstation
Sectra MPR Package
Sectra 3D Package
Common Name: Picture Archiving and Communications System
Classification Name: Image Processing System (LLZ) (21 CFR § 892.2050)

Predicate Device:

Applicant: Sectra Imtec AB
510(k) Number: K033712
Device: Sectra IDS5 Radiology Workstation

Device Description:

The Sectra IDS5 Radiology Workstation with Sectra 3D and MPR Packages is mainly a software product. It is used for visualization and processing of digital radiology images. The IDS5 is used as a client together with a Sectra provided server (Class I Exempt). The system runs on PCs under the Windows operating systems. Most notably two or more monitors are used.

The Sectra IDS5 Radiology Workstation is in fact a family of devices, including several workstations or types of workstations, e.g. the following:

- Primary diagnostics workstation and the most powerful version of IDS5. It contains tools for assisting the radiologist in making a diagnosis.

- Dedicated workstation for mammography. It has all functionality as an IDS5/dx.net but with an additional mammography package.
- Quality assurance workstation, mainly used by the technologists to prepare the images for the reviewing radiologist.
- Clinicians workstation used by the clinicians within the hospital to view the radiology images and to read the radiology report.
- “Web” workstation that can be used by remote clinics to view images and radiology reports.
- “At-home” workstation that can be used by the radiologist over a low bandwidth connection.

Indications for Use:

The Sectra IDS5 device is intended for the manipulation and displaying of x-ray images, including mammograms. It can show images from different modalities and interfaces to various image storage and printing devices using DICOM or similar interface standards.

Device options make possible mammography reading, telecommunications; fast demonstration; prosthesis CAD; 3-D and angiography, etc.; and teleconferencing.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics:

The system The IDS5 Radiology Workstation with Sectra 3D and MPR Packages will runs under the Window 2000 and Windows XP operating system for PCs (as a minimum and depending upon system configuration)¹. The requirements on hardware are quite ordinary for a system used for displaying images. Most notably up to four monitors can be used.

Performance Data:

The subject device is developed according to ISO 9001:2000 and complies with ACR/NEMA Digital Imaging Communications in Medicine version 3.0.

Conclusion:

Similar to the predicate device, the IDS5 Radiology Workstation with Sectra 3D and MPR Packages does not contact the patient, nor does it control any life sustaining devices. Images and information being reviewed, processed, relayed, and or transmitted are interpreted by a physician or trained medical personnel, providing ample opportunity for competent human intervention. The device and the predicate device share the same certification or conformance to performance standards and both function as Image Processing System (LLZ). Device failures, which might result in partial or failed transmissions, images, or data, may be recovered from storage or re-transmission after correcting the problem(s). Passwords are required for operation and to protect against unauthorized use.

¹ Windows NT is supported for IDS5/web and IDS5/cl.net only.

Based on the information supplied in this Special 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.

A handwritten signature in black ink, appearing to read 'Peter Andersson', with a long horizontal flourish extending to the right.

Peter Andersson
Regulatory Affairs Officer
Sectra Imtec AB
Linköping, Sweden



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2004

Sectra Imtec AB
% Mr. Carl Alletto
US Agent
OTech, Inc.
1600 Manchester Way
CORNITH TX 76210

Re: K040376
Trade/Device Name: Sectra IDS5 Radiology Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 2, 2004
Received: April 5, 2004

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

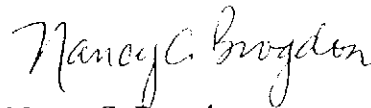
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K040376

Device Name: IDS5 Radiology Workstation by Sectra Imtec AB

Indications For Use:

The Sectra IDS5 device is intended for the manipulation and displaying of medical, including mammograms. It can show images from different modalities and interfaces to various image storage and printing devices using DICOM or similar interface standards.

Device options make possible mammography reading, telecommunications; fast demonstration; prosthesis CAD; 3-D and angiography, etc.; and teleconferencing.

Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

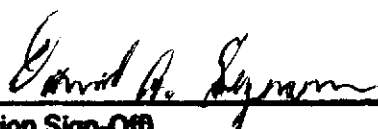
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over -The-Counter Use ☐


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040376